

Initial Report of Financial Interests in Substantially Affected Organizations for Employees of the National Institutes of Health

HHS Supplemental Ethics Regulation 5 CFR 5501.110

HHS Supplemental Financial Disclosure Regulation 5 CFR 5502.107

Department of Health and Human Services

Form 716



Initial Due Date October 31, 2005

Extended Due Date

Date Report Filed

I. Employee Information

1. Name

Last _____

First _____ MI _____

2. Agency

IC/Office _____

Subcomponent _____

3. Title of Position

4. Grade/Step

5. Federal Salary

6. Appointment Type

" PAS/PA " Non-Career SES " Schedule C
" Career SES " General Schedule " Title 42
" Commissioned Corps " Other _____

7. Financial Disclosure Filing Status

" Public (SF 278)
" Confidential (OGE 450)
" None

8. Office Address

Street _____

City _____

State _____ Zip _____

9. Office Contact Information

Telephone () -

Fax () -

Cell () -

E-Mail _____

10. Name of Immediate Supervisor

11. Supervisor Contact Information

Telephone () -

Fax () -

Cell () -

E-Mail _____

12. Title of Supervisor

Agency Use Only

II. Summary of Conflict of Interest Law

1. Disqualification

Under the Federal criminal conflict of interest statute, 18 U.S.C. 208, you are prohibited from working on any government matter that directly and predictably affects your own or an imputed financial interest. If your spouse or minor child(ren), among others, have financial interests, such as stocks, stock options, bonds, or sector mutual funds, that are affected by government matters on which you work, you are disqualified to the same extent as if those investments were your own. You would violate the law if you participate personally, or by directing subordinates, and if you contribute substantially to the resolution of the matter. The test is whether the matter itself affects a financial interest of a company in which you are invested, and not whether your actions affect the company. Therefore, you need not be a decision-maker for a violation to occur. Rendering advice or arguing the merits of a study or policy, even if your views are not accepted, can be substantial participation in the matter.

Certain regulatory exemptions found at 5 CFR Part 2640, which are tied to the type and value of the conflicting holdings, may permit you to participate despite the potential for conflict. For example, if the combined value of publicly traded securities you own individually and with others does not exceed certain monetary caps, you are free to work on a matter affecting those holdings. Consult the regulations and your Deputy Ethics Counselor (DEC) for details. On the other hand, if your individual and imputed financial assets exceed those limits or otherwise do not qualify for a regulatory exemption (for example, stock options or nonpublicly traded securities are not covered), you must disqualify yourself from participation in the matter if the company that issued the securities potentially faces any gain or loss from the resolution of the matter. A violation can occur even though the stock price is unaffected. The question essentially is whether the company, from a financial point of view, would care how the government matter turns out.

The disqualification required by the statute is often called a “recusal.” If your holdings create a conflict, you cannot pick and choose among the various aspects of a particular matter and stay away only from the important decisions. Such incomplete recusals will not protect you from a criminal conflict of interest violation. Unless a waiver, approved in advance, identifies specific permitted activities, you must refrain entirely and absolutely from participating personally and substantially in a government matter that affects your own or imputed financial interests.

You must recuse not only from those government matters that specifically involve or affect the company that issued the stock, but from those matters that affect generally the industry or economic sector in which the company operates. Your obligation to recuse is one for which you are personally responsible and is not contingent upon someone telling you to do so. Recusal is triggered immediately whenever a matter arises that would pose a conflict. If these recusal obligations impede your ability to do your work, the agency can address the conflict through a waiver or by ordering divestiture. An advance waiver to allow your participation in conflicting matters may be granted only if your appointing authority concludes that the interest is not so substantial as to be deemed likely to affect the integrity of the services which the Government expects of you.

2. Divestiture

If your ability to do your job would be materially impaired because you have to recuse from working on central or critical matters, or agency efficiency would be adversely affected because your work cannot be readily assigned to another employee, then the agency can require you to divest the conflicting financial interest. In addition, the HHS Supplemental Ethics Regulation at 5 CFR 5501.110, among other limitations, bars senior NIH employees, their spouses, and minor children from acquiring or holding financial interests in substantially affected organizations (SAOs), such as biotechnology, pharmaceutical, or medical device companies, that exceed \$15,000 in value in any one holding or in sector mutual funds that state in their prospectus the objective of investing in SAOs that, when combined, exceed \$50,000 in value.

3. Monitoring Obligations

If you are a senior NIH employee subject to the prohibited holdings rule at 5 CFR 5501.110, the value of any residual holdings that you are allowed to keep cannot exceed the applicable caps (\$15,000 single issuance/\$50,000 combined SAO sector funds). If you are not a senior NIH employee, you must limit any retained SAO holdings that pose a conflict to an amount at or beneath the applicable regulatory exemption amounts in 5 CFR 2640.202, or you will have to recuse immediately from government matters affecting the conflicting financial interests. You must monitor capital appreciation and dividend reinvestments to ensure that the caps are not exceeded. Issuing a standing sell order to your broker to limit your positions in conflicting stock may be necessary.

In order to avoid conflicts, you will need to monitor the business activities of the companies in which you invest and be familiar with their commercial products, including those publicly disclosed to be under research and development. This task can be exacerbated by mergers, acquisitions, joint ventures, partnerships, and even name changes, within SAO industries that, on any given day, may make it difficult for you to know whether a situation requiring your disqualification has arisen.

You must assess on an ongoing basis whether any company in which you are invested would be affected financially by the resolution of government matters on which you presently or in the future are assigned to work. Therefore, you must be attentive to any change in your duties or assignments and consider how the new matters on which you work will affect companies that you previously thought posed no conflict.

In addition, although the reporting obligation for this form centers on SAOs, remember that your holdings in non-SAO securities may require recusal or divestiture as well. You must be constantly alert to other situations that pose conflicts, for example, procuring information resources from outside contractors when you have considerable holdings in data management, computer, or information processing firms.

4. Reporting Obligation

This form has been developed to assist you in complying with the SAO reporting obligation specified in 5 CFR 5502.107(c)(4). The provision requires a one time, initial report of financial interests in SAOs to be filed by all employees, other than special Government employees, on duty at the NIH on August 31, 2005, who were classified as public or confidential financial disclosure report filers or who serve as clinical investigators. The identifying information and value of the holdings must be current as of the date of filing the report. The filing deadline is October 31, 2005.

If, at any time after you file the HHS Form 716, you, your spouse, or minor child(ren) should acquire a financial interest in an SAO, for example, through marriage, gift, or inheritance, you are required by 5 CFR 5502.107(c)(3) to file a similar report, HHS Form 717-1, within 30 days of acquiring the financial interest. If the financial interest poses a conflict and a regulatory exemption does not apply, you must disqualify yourself immediately from government matters affecting the holding. Your obligation to recuse is one for which you are personally responsible; the disqualification applies without regard to the circumstances under which you obtained the asset; and it is not contingent upon prior notification to recuse nor dependent upon the filing of a disclosure report.

III. Financial Interests in Substantially Affected Organizations

1. Report For you, your spouse, and minor child(ren), report all financial interests, such as stocks, bonds, stock options, and other investments or ownership interests, in **substantially affected organizations** held as of the date you file this report. Include any sector mutual fund that states in its prospectus the objective of concentrating its investments in the securities of substantially affected organizations. A "substantially affected organization" means: (1) a biotechnology or pharmaceutical company; a medical device manufacturer; or a corporation, partnership, or other enterprise or entity significantly involved, directly or through subsidiaries, in the research, development, or manufacture of biotechnological, biostatistical, pharmaceutical, or medical devices, equipment, preparations, treatments, or products; (2) any organization a majority of whose members are these types of entities; and (3) any other organization determined by the agency to be substantially affected by the programs, policies, or operations of the NIH. **Consult the NIH Deputy Ethics Counselor or the DEC for your institute or center for assistance in identifying companies in the biotechnology, biostatistics, pharmaceutical, medical device, and related industries and any other organizations that are substantially affected.**

Describe the financial interest, indicate the type of investment, and if the interest was acquired as a form of compensation or other benefit derived from prior or current employment with a substantially affected organization, check the employee benefit (EB) column. Provide the value of the financial interest (actual dollar amount as of the filing date), and specify whether the financial interest is owned individually (I), by your spouse (S), or minor child(ren) (MC), or jointly (J). If held jointly with a spouse, minor child(ren), or others (O), indicate the co-owner(s), for example, J/S, J/MC, or J/O. Indicate the relationship of any co-owners other than a spouse or minor child in the Comments section in Part III, Box 3.

Senior NIH employees only must answer the questions in Part III, Box 2. All employees must sign and date the certification in Part III, Box 4. File this report with your DEC by October 31, 2005.

If none, check the box. **NONE** 

Letter Block	Description	Type of Investment	EB	Value \$	I/S/MC J/O
Example	Zyex Pharmaceuticals	Bonds		7,205	S
Example	Medical Products Technology Co.	Common stock in 401(k) pension from prior employment	U	56,382	I
Example	Orion Advisors Biotech Fund	SAO Sector Fund		18,855	J/S
A					
B					
C					
D					
E					
F					
G					
H					

Letter Block	Description	Type of Investment	EB	Value \$	I/S/MC J/O
I					
J					
K					
L					

2. QUESTIONS FOR SENIOR NIH EMPLOYEES ONLY (NIH Director, NIH Deputy Directors, OD Senior Staff who are Direct Reports to the NIH Director; IC Directors, IC Deputy Directors, IC Scientific Directors, and IC Clinical Directors; Extramural Program Officials who are Direct Reports to an IC Director; and Designated Equivalent Positions)

a. Does any equity interest in a substantially affected organization listed above in Part III, Box 1, constitute 1% or more of the total outstanding equity of the organization?

" Yes *(If this box is checked, identify the financial interest and explain in Part III, Box 3.)*

" No

b. Does the actual value of the holdings listed above in Part III, Box 1, in substantially affected organizations and sector mutual funds that state in their prospectus the objective of investing in substantially affected organizations, when totaled, account for 50% or more of the total value of the combined investment portfolio of you, your spouse, and minor child(ren)?

" Yes

" No

3. Comments *(If additional space is required, use the space provided at the end of this form.)*

4. Certification

I certify that I have read and understand the Summary of Conflict of Interest Law in Part II, that to the extent any aspect of the description was unclear to me, I have asked and received clarification from the DEC, and that the statements I have made on this form are true, complete, and correct to the best of my knowledge.

Employee Signature

Date

IV. Supervisor Review

Supervisor review is not required for reports submitted by senior NIH employees who are subject to the SAO prohibited holdings rule at 5 CFR 5501.110. For all other employees, input from the supervisor must be obtained as specified below.

1. Description of Potential Conflicts *For each interest in a substantially affected organization reported in Part III, Box 1, indicate whether the employee would be expected to participate in proposing, planning, advising, deciding, or implementing an official action, either individually or by actively directing subordinates, that would be of significance to the resolution of government matters that affect the identified companies specifically or generally as part of an industry class. Indicate whether a potential conflict would arise and explain your answer.*

2. Resolution of Potential Conflicts *The employee must be disqualified from participating personally and substantially in government matters that directly and predictably affect a conflicting financial interest, unless the conflict has been waived by the employee's appointing authority or a regulatory exemption applies. The recusal obligation extends not only to particular matters that specifically involve or affect the issuer of the identified securities, such as a contract, CRADA, or clinical trial involving the company's products or those of certain competitors, but to those matters that affect generally the industry or economic sector in which the company operates, such as policy decisions on research priorities.*

a. Reassignment of Work to Another Individual *For each interest in a substantially affected organization reported in Part III, Box 1, indicate whether the employee's work assignments that potentially affect the company specifically or that could affect the company generally as a part of an industry class can be readily assigned to another individual. Explain your answer.*

b. Nature of Work Assignments *For each interest in a substantially affected organization reported in Part III, Box 1, indicate whether the employee's work assignments that potentially affect the company specifically or that could affect the company generally as a part of an industry class would be considered central or critical to the performance of the employee's official duties. Explain your answer.*

c. Material Impairment of Ability to Perform Duties of Position *Indicate whether the employee's ability to perform the duties of his or her position would be materially impaired if the employee were disqualified from participating in government matters affecting the identified financial interests. Explain your answer.*

3. Comments *Use this space to state any concerns or questions to be resolved by the DEC.*

Supervisor Signature

Date

V. Deputy Ethics Counselor Determination

1. Name of Deputy Ethics Counselor

2. Contact Information

Telephone () -

Fax () -

3. Title of Deputy Ethics Counselor

Cell () -

E-Mail

4. Organization

5. Determination

After reviewing the disclosed information, I have determined, pursuant to 5 CFR 2635.403, that the identified employee, spouse, and/or minor child(ren) must sell or otherwise divest the reported financial interests, and/or the employee must recuse from personal and substantial participation in any particular matter that will directly and predictably affect the reported interests, as follows:

“ Total Divestiture of the Financial Interests Specified in the Box(es) Below REQUIRED on or before the Date Specified in Part V, Box 6 (If this box is checked, the DEC has determined that the employee cannot retain the financial interest(s) reported in Part III, Box 1, identified by the corresponding Letter Block listed below, because the holdings are stock options, nonpublicly traded securities, or other financial interests for which a regulatory exemption in 5 CFR Part 2640 or a waiver under 18 U.S.C. 208(b) is unavailable. The DEC has determined that any work assignments involving specific or general matters from which the employee will be disqualified as a result of the employee's individual or imputed ownership of the financial interest cannot be readily assigned to another individual and/or are so central or critical to the performance of the employee's official duties that the employee's ability to perform the duties of his or her position would be materially impaired.)

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“ Partial Divestiture of the Financial Interests Specified in the Box(es) Below REQUIRED on or before the Date Specified in Part V, Box 6 (If this box is checked, the DEC has determined that the employee cannot retain that portion of the financial interest(s) reported in Part III, Box 1, identified by the corresponding Letter Block listed below, that exceeds the de minimis holding amounts permitted by regulatory exemptions in 5 CFR Part 2640. The DEC concludes that a waiver under 18 U.S.C. 208(b) is not warranted and finds that any work assignments involving specific or general matters from which the employee will be disqualified as a result of the employee's individual or imputed ownership of the financial interest cannot be readily assigned to another individual and/or are so central or critical to the performance of the employee's official duties that the employee's ability to perform the duties of his or her position would be materially impaired.)

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“ Partial Divestiture of Financial Interests Held by Senior NIH Employees Specified in the Box(es) Below REQUIRED on or before the Date Specified in Part V, Box 6 *(If this box is checked, the DEC has determined that the employee cannot retain that portion of the financial interest(s) reported in Part III, Box 1, identified by the corresponding Letter Block listed below, that exceeds the de minimis holding amounts in 5 CFR 5501.110 (\$15,000 single issuance/\$50,000 combined sector mutual funds) because the financial interests are prohibited for senior NIH employees.)*

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“ Recusal with respect to Particular Matters Affecting the Financial Interests Specified in the Box(es) Below REQUIRED *(If this box is checked, the DEC has determined that the employee may retain the conflicting financial interest(s) reported in Part III, Box 1, identified by the corresponding Letter Block listed below, but the employee must be disqualified from participating personally and substantially in government matters that directly and predictably affect such interest(s). The DEC concludes that a waiver under 18 U.S.C. 208(b) is not warranted and a regulatory exemption does not apply. The recusal obligation extends not only to particular matters that specifically involve or affect the issuer of the identified securities, but to those matters that affect generally the industry or economic sector in which the issuer operates. The DEC finds that any work assignments involving specific or general matters from which the employee will be recused can be readily assigned to another individual and are not so central or critical to the performance of the employee’s official duties that the employee’s ability to perform the duties of his or her position would be materially impaired.)*

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“ Divestiture or Recusal with respect to the Financial Interests Specified in the Box(es) Below NOT CURRENTLY REQUIRED *(If this box is checked, the DEC has determined that the employee may retain the financial interest(s) reported in Part III, Box 1, identified by the corresponding Letter Block listed below, because the reported values do not exceed the de minimis holding amounts permitted by regulatory exemptions in 5 CFR Part 2640, or such interests do not currently pose a conflict in light of the employee’s anticipated duties and responsibilities. The employee must monitor the value to ensure that capital appreciation and dividend reinvestments do not cause the holdings to exceed applicable caps. The employee must recuse, and may be required to divest, if the caps are exceeded or if a change in duties and responsibilities creates a conflict that previously did not exist.)*

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“ Divestiture or Recusal NOT CURRENTLY REQUIRED for Financial Interests in Substantially Affected Organizations Because the Employee Reported NONE in Part III

“ Other Disposition *(Specify in the space provided at the end of this form)*

6. Divestiture Date *(Divestiture must be completed on or before the following date.)*

January 30, 2006

DEC Signature

Date

VI. Certificate of Divestiture

1. Capital Gains Tax Deferral Section 1043 of the Internal Revenue Code (26 U.S.C. 1043) and the regulations issued by the Office of Government Ethics (OGE) may allow an eligible person (including an employee, or the employee's spouse or minor or dependent children) to defer paying capital gains tax on property sold to comply with conflict of interest requirements. To defer the gains, an eligible person must obtain a legal document called a Certificate of Divestiture (CD) from the OGE Director **before** selling the property, after which the eligible person is required to reinvest within 60 days the proceeds of the sale in "permitted property," which is either an obligation of the United States, such as a Treasury security, or a diversified investment fund, such as a diversified mutual fund. More information about Certificates of Divestiture can be found at <http://ethics.od.nih.gov/Topics/divest.htm>.

Note that assets held in certain investment vehicles, such as an Individual Retirement Account (IRA) or 401(k), or other tax deferred assets not subject to capital gains tax are ineligible for a CD.

2. Certificate of Divestiture Election Indicate whether you or any eligible person requests a CD.

Yes (If "yes," you and/or other eligible persons anticipate realizing a capital gain on the sale of the conflicting financial interests identified by the DEC in Part V and request that a Certificate of Divestiture be issued. You and/or other eligible persons agree to divest the holdings, as directed, on or before **January 30, 2006**, and to reinvest the proceeds in permitted property within 60 days after divesting the identified holdings. You must abide by applicable recusal obligations pending the disposition of the conflicting financial interests. **In order to process your request, you must supply the information specified in Part VI, Box 3, and resubmit this form promptly to your DEC.** You must either have been notified by the DEC of the issuance of a CD or have the document in your possession prior to selling the conflicting financial interests in order to receive the tax deferral. Complete Part VII of this form when you have fully divested all prohibited holdings, and then resubmit this form promptly to your DEC to document compliance.)

No (If "no," the conflicting financial interests identified by the DEC in Part V must be sold or otherwise divested and all necessary transaction(s) completed on or before **January 30, 2006**. Sign and date below to confirm your decision. Complete Part VII when you have fully divested all holdings in substantially affected organizations in accordance with the DEC determination, and then resubmit this form promptly to your DEC to document compliance.)

3. Description of Financial Interests In the space provided at the end of this form or in an attached list, describe how you and/or the eligible person(s) acquired the identified holdings and provide a full and specific description of the property that will be divested. Identify the record owner(s) and type of ownership. For example, if the property is corporate stock, the exact number of shares must be included: "Acme Co. common stock 125.750 shares John Doe and wife Jane Doe as JTWROS (joint tenants with right of survivorship)."

4. Certification

I confirm the election indicated above and certify that the statements I have made on this form and any attachments are true, complete, and correct to the best of my knowledge.

Employee Signature

Date

VII. Compliance

1. Divestiture *Describe the steps that you have taken to comply with your divestiture obligation and indicate the date by which you completed all required transactions.*

Date Divestiture Completed _____

2. Recusal *Describe the actions you have taken to fulfill your recusal obligation, indicate the screening mechanism(s) that you use to avoid participation in particular matters from which you are disqualified, and identify the individual(s) to whom responsibility for such matters has been reassigned or delegated.*

3. Monitoring Obligation *Describe the monitoring actions you will undertake to ascertain on a continuing basis the value of your individual and imputed holdings and to ensure that applicable caps are not exceeded. Identify the means by which you will be informed of the business activities conducted by the companies in which you are invested. Describe the steps you will take to assess whether any company in which you are invested would be affected financially by the resolution of government matters on which you presently or in the future are assigned to work.*

4. Certification

I certify that I have read and understand the Summary of Conflict of Interest Law in Part II; that, to the extent any aspect of the description was unclear to me, I have asked and received clarification from the DEC; that, where applicable, I have sold or otherwise divested the financial interests in substantially affected organizations identified by the DEC in Part V, Box 5; that I will recuse, as required by law, from participation in specific party matters affecting any identified financial interest resulting from ownership of securities that I have been permitted to retain; and that I will recuse, as required by law, from participation in general matters that affect the industry or economic sector in which the issuer of such securities operates. I acknowledge my personal obligation under criminal conflict of interest law to monitor the value of my individual and imputed holdings, to be informed of the business activities conducted by the companies in which I am invested, to assess whether any company in which I am invested would be affected financially by the resolution of government matters on which I presently or in the future am assigned to work, and to recuse whenever the type or value of any conflicting financial interest exceeds or is not covered by a waiver or regulatory exemption. I certify that the statements I have made on this form are true, complete, and correct to the best of my knowledge.

Employee Signature

Date

ADDITIONAL SPACE

Identify the part and box to which the additional information refers.

PRIVACY ACT STATEMENT

The Ethics in Government Act, 5 U.S.C. App. § 101, *et seq.*, Executive Order 12674, as amended by Executive Order 12731, Sections 301 and 7301 of Title 5 of the U.S. Code, and Sections 2634.103, 5501.110, and 5502.107 of Title 5 of the Code of Federal Regulations authorize the collection of this information. Disclosure of this information is mandatory for employees of the National Institutes of Health (NIH), except Special Government Employees, who were on duty on August 31, 2005, and who were required to file a public or confidential financial disclosure report or designated as a clinical investigator as defined in 5 C.F.R. § 5502.107(b)(1). Falsification of information or failure to file or report information required to be reported may subject the employee to disciplinary action. Knowing and willful falsification of information required to be reported may subject the employee to criminal prosecution. The primary use of this information is to assist NIH supervisors, other management officials, and agency ethics officials in ensuring compliance with the prohibited holdings provisions of the HHS Supplemental Ethics Regulation applicable to senior NIH employees and the conflict of interest provisions of the Standards of Ethical Conduct applicable to all NIH employees. The information may also be used to counsel employees concerning their ethics responsibilities and to prevent violations of the statutes, regulations, and executive orders governing employee conduct. The information is also requested, pursuant to 5 C.F.R. §§ 2638.203(b)(9),(10), and (11), for the purpose of evaluating ethics program administration, as well as the Department's supplemental ethics regulations, to determine their continued adequacy and effectiveness in relation to current agency responsibilities and to ensure that prompt and effective action is taken to remedy violations or potential violations, or appearances thereof, of conflict of interest and related ethics provisions. Additionally, this information may be disclosed to: (1) the Office of Personnel Management, Office of Government Ethics, Merit Systems Protection Board, Office of the Special Counsel, Equal Employment Opportunity Commission, Federal Labor Relations Authority, Federal Service Impasses Panel, Federal Mediation and Conciliation Service, and an arbitrator, in carrying out their functions; (2) a Federal, State, or local agency charged with investigating or prosecuting violations of, or implementing, the law, in the event there is an indication of a violation or potential violation of civil, criminal or regulatory law; (3) a Federal, State, or local agency maintaining enforcement records or other pertinent records, such as current licenses, if necessary to obtain a record relevant to an agency decision concerning the hiring or retention of an employee, the issuance of a security clearance, the letting of a contract, or the issuance of a license, grant or other benefit; (4) the National Archives and Records Administration or the General Services Administration in records management inspections; (5) the Office of Management and Budget during legislative coordination on privacy relief legislation; (6) Federal agencies with power to subpoena other Federal agencies' records; (7) a court or party in a court or Federal administrative proceeding if the Government is a party or in order to comply with a judge-issued subpoena; (8) private firms with which the Department may contract for the purpose of collating, analyzing, aggregating or otherwise refining records; (9) a Member of Congress or a Congressional office, pursuant to an inquiry made at the request of the individual who is a subject of the record; (10) the Department of Justice in defense of litigation; and (11) contractors and other non-Government employees working for the Federal Government to accomplish a function related to an Office of Government Ethics Government-wide system of records. This confidential report will not be disclosed to any requesting person unless authorized by law. See the OGE/GOVT-2 Government-wide executive branch system of records.



Department of Health and Human Services
Office of the Secretary
Office of the General Counsel
Ethics Division
Washington, DC 20201

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